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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,931	05/10/2002	Luc Varin	09680.0352US01	8743
23552 7590 04/18/2007 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER BAUM, STUART F	
			ART UNIT	PAPER NUMBER
			1638	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/18/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/019,931

Applicant(s)

VARIN ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2006 and 12 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-96 is/are pending in the application.
- 4a) Of the above claim(s) 91-96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/17/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendments filed 11/7/2006 and 1/12/2007 have been entered.
2. Claims 74-96 are pending.
Claims 1-73 have been canceled.
Claims 74-96 have been newly added.
3. Newly submitted claims 91-96 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claims 74-90, drawn to a method for accelerating flowering in a plant comprising increasing the level of 11-hydroxyjasmonic acid or 12-hydroxyjasmonic acid by decreasing the expression of a sulfotransferase of SEQ ID NO:3 or a sequence having at least 60% homology to SEQ ID NO:3 or a genetically modified plant produced by said method.

Group II, claims 91-96, drawn to a method for accelerating flowering in a plant comprising decreasing the level of sulfate ester of 12-hydroxyjasmonic acid or sulfate ester of 11-hydroxyjasmonic acid by increasing the expression of a sulfotransferase of SEQ ID NO:3 or a sequence having at least 60% homology to SEQ ID NO:3.

Pursuant to 37 CFR 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited method and product. Further pursuant to 37 CFR 1.475(d), the ISA/US considers that any feature which the subsequently recited products or methods share with the main invention does not constitute a

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special technical feature within the meaning of PCT Rule 13.2 and that each of such products or methods accordingly defines a separate invention.

Applicants provisionally elected Group IV (renamed Group I in this instance) in the response filed 7/28/2004.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 91-96 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 74-90, including SEQ ID NO:1 and SEQ ID NO:3 are examined in the present office action.
5. Rejections and objections not set forth below are withdrawn.
6. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 74-90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to recite "at least 60% homology to SEQ ID NO:3" or "at least 80% homology to SEQ ID NO:3". Applicants fail to point to support for the phrase in the instant specification. Upon a cursory search of the specification, support could not be found. Applicants are required to point to support for "at least 60% homology to SEQ ID NO:3" and "at least 80% homology to SEQ ID NO:3" or to amend the claims to delete the NEW MATTER.

Written Description

8. Claims 74-90 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for accelerating flowering in a plant comprising increasing 11-hydroxyjasmonic acid or 12-hydroxyjasmonic acid by decreasing the expression of a sulfotransferase having at least 60% or 80% homology to SEQ ID NO:3, or a method for producing a transgenic plant which flowers early comprising introducing into a cell of a plant a sequence of nucleotides antisense to a nucleic acid sequence coding for a polypeptide having at least 60% or 80% homology to SEQ ID NO:3, or a plant obtained by said method, or a method for accelerating flowering in a plant comprising increasing the expression of a sequence having at least 60% or 80% homology to SEQ ID NO:3.

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Applicants disclose a nucleic acid sequence encoding an Arabidopsis 12-hydroxyjasmonic acid sulfotransferase (AtST2a) of SEQ ID NO:1 (page 5, line 13-17 and page 6, lines 29-32).

Applicants do not identify essential regions of the protein of SEQ ID NO:3, nor do Applicants disclose any polynucleotides encoding any polypeptides that encode a sulfotransferase having at least 60% homology to SEQ ID NO:3 and having the same activity as the protein of SEQ ID NO:3.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences from a representative number of plant species encoding a sulfotransferase having the same activity as the protein of SEQ ID NO:3. Applicants only describe a single cDNA sequence of SEQ ID

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NO:1. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the protein of SEQ ID NO:3, it remains unclear what features identify an Arabidopsis hydroxyjasmonic acid sulfotransferase protein of SEQ ID NO:3. Since the genus of hydroxyjasmonic acid sulfotransferase proteins has not been described by specific structural features the specification fails to provide an adequate written description to support the breadth of the claims.

Applicant's arguments filed 11/17/2006 have been fully considered but they are not persuasive.

Applicants contend the present application contains the motifs that are well-known to be present in all soluble sulfotransferases that have been characterized (page 9 of Remarks, 2nd full paragraph). Applicants contend one skilled in the art can conduct a blast search of sequences at NCBI to find other genes encoding sulfotransferases and to also find conserved domains and assess for sulfotransferase activity as described in the 1.132 Declaration filed 11/17/2006 by Luc Varin (*Ibid* and page 10 of Remarks, 1st full paragraph). Applicants state "Hence, in this particular case, it is not necessary to disclose in the present specification all sequences having a sulfotransferase activity or coding for a sulfotransferase as this information is readily available to those skilled in the art" (page 10 of Remarks, 1st full paragraph). Applicants contend that disclosing structural features common to members of the claimed genus of polynucleotides is unnecessary since several sequences encoding sulfotransferases are known to have been present in databases at the time of filing the instant application (page 10 of Remarks, 2nd full paragraph).

The Office contends that for claims drawn to a sulfotransferase of SEQ ID NO:3, Applicants have satisfied the written description requirement. But, for claims drawn to sulfotransferases exhibiting less than 100% sequence identity to SEQ ID NO:3, Applicants have not satisfied the written description requirement. Applicants have not disclosed a representative number of polynucleotides encoding sulfotransferases that have the same activity as Applicants' SEQ ID NO:3, wherein the activity of said sulfotransferases affects flowering in the same way as does SEQ ID NO:3. The Office contends Applicants have not disclosed essential regions of said sulfotransferase and Applicants have not disclosed a structure function relationship of conserved domains and the activity of said sulfotransferase. Therefore, the Office contends that at the time of filing, Applicants were not in possession of the broadly claimed invention.

Scope of Enablement

9. Claims 74-90 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing the time to flowering in Arabidopsis plants comprising transforming said plants with the Arabidopsis AtST2a genomic sequence of SEQ ID NO:1 encoding SEQ ID NO:3, operably linked to a promoter in antisense orientation, wherein the levels of 12- or 11-hydroxyjasmonic acid are increased relative to non-transgenic plants, does not reasonably provide enablement for any method that accelerates flowering in a plant comprising decreasing expression of SEQ ID NO:3 or a sequence having at least 60% or 80% homology to SEQ ID NO:3, or wherein the method comprises a nucleic acid molecule in antisense orientation wherein the nucleic acid molecule encodes a sulfotransferase having less than 100% identity to SEQ ID NO:3, or wherein the method comprises applying an inhibitor of

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said sulfotransferase, or a method for accelerating flowering comprising decreasing sulfate ester of 11- or 12-hydroxyjasmonic acid comprising increasing the expression of SEQ ID NO:3 or a sequence having at least 60% or 80% homology to SEQ ID NO:3.

This rejection is maintained for the reasons of record set forth in the Official action mailed 5/17/2006. Applicant's arguments filed 11/17/2006 have been fully considered but they are not persuasive.

Applicants contend that Examples 2 and 3 disclose Arabidopsis plants that flower early (page 12 of Remarks, 1st full paragraph). Applicants contend that given the disclosure in the specification and the teachings in the 1.132 Declaration, one skilled in the art can practice the claimed invention without undue experimentation (page 12 of Remarks, 2nd full paragraph).

The Office contends that Applicants have exemplified a method for accelerating flowering time in Arabidopsis comprising transforming Arabidopsis with SEQ ID NO:1 in antisense orientation. The Office contends that Applicants' 1.132 Declaration discloses a method for accelerating flowering time in Brassica napus comprising transforming a Brassica napus plant with the coding sequence of BnST2a in antisense orientation. The Office contends Applicants are not enabled for a method for accelerating flowering in any plant comprising transforming any plant with any nucleic acid in antisense orientation wherein said nucleic acid encodes a protein having at least 60% homology to SEQ ID NO:3. The Office contends Applicants have not shown that the Arabidopsis AtST2a in antisense orientation can be used to down regulate the endogenous BnST2a gene in Brassica napus even though at the protein level, AtST2a and BnST2a exhibit 83% amino acid identity (See page 13 of 1.132 Declaration). The Office contends that the state-of-the-art teaches antisense technologies require a very high degree

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of sequence complementarity between the antisense molecule and the target sequence, as discussed in the previous office action. Therefore, undue trial and error experimentation would be required by one of skill in the art to practice the broadly claimed invention.

Applicants contend that the Harms et al reference cited in the enablement rejection is not germane to the present invention (paragraph bridging pages 12-13 of Remarks).

The Office contends the Harms et al reference was cited as an example of the state-of-the-art of modifying derivatives of jasmonic acid to achieve a particular phenotype.

Applicants contend that given the teachings in the specification and the teachings in the 1.132 Declaration, one of skill in the art could easily retrieve other sulfotransferase coding genes having the same biochemical function as AtST2A and one of skill in the art could predict which nucleic acids that are at least 60% homologous to SEQ ID NO:1 would encode a protein with the same activity as the protein encoded by SEQ ID NO:1 (paragraph bridging pages 13-14 of Remarks). Applicants assert that the citations by Bowie et al and McConnell et al are not relevant to the present invention (page 14 of Remarks, 1st full paragraph to page 15 of Remarks, 2nd full paragraph).

The Office contends Applicants have not disclosed a structure function relationship between nucleic acid sequences and sulfotransferases that have the same activity as Applicants' SEQ ID NO:3 and wherein the nucleic acid molecule can be used to down regulate any sulfotransferase and produce the desired accelerated flowering time (see above discussion). The Office contends Applicants have not produced any plant having accelerated flowering time by increasing the level of 11- or 12-hydroxyjasmonic acid by decreasing the expression of a sulfotransferase of SEQ ID NO:3 or any sequence having at least 60% homology to SEQ ID

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NO:3, by any method. Applicants have only taught transforming Arabidopsis with the Arabidopsis AtST2a genomic sequence of SEQ ID NO:1 encoding SEQ ID NO:3, operably linked to a promoter in antisense orientation.

Applicants contend one skilled in the art would be apprised of the necessary experimentation required to work with antisense technology that would over-come the unpredictability of using antisense as taught by Bryant (paragraph bridging pages 15-16). Applicants contend one skilled in the art would know which region of the respective polynucleotides could be used to amplify any of the polynucleotides or which region could be used as a probe to isolate any of the polynucleotide sequences, as this is the approach that was used to isolate BnST2 in the first example of the annexed Declaration under Rule 1.132 (page 16 of Remarks, bottom paragraph). Applicants contend conserved domains present in all sulfotransferases were known by the time of filing. Applicants reference Varin et al., 1992 PNAS 89(4):1286-1290 (page 17 of Remarks, top paragraph). Applicants contend that plant genomes contain only a limited number of different sulfotransferases and it would be very easy to assay all of them (page 18 of Remarks, 1st and 2nd paragraphs).

The Office contends that the Varin et al reference discloses two plant flavonol sulfotransferases and it is not clear if the disclosed cDNA sequences can be used in Applicants' invention even though they encode a sulfotransferase. It is clear from Applicants 1.132 Declaration that there exist nucleic acid molecules encoding sulfotransferases that are not operable in Applicants' invention. The Office contends Applicants have not disclosed enough information for one of skill in the art to practice the broadly claimed invention. The Office contends Applicants have not disclosed which conserved regions of a sulfotransferase operable

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in Applicants' invention can be used as probes or primers. The Office acknowledges that the tools or protocols for practicing the invention are available, but the Office contends, one of skill in the art would have to conduct an excessive amount of trial and error experimentation to identify and isolate those molecules that will work in Applicants' invention given the lack of disclosure. Applicants' claims are drawn to 60% homology to SEQ ID NO:3, but Applicants have not taught by way of disclosure or example any nucleic acid sequence encoding a protein having at least 60% homology to SEQ ID NO:3 that is operable in Applicants' invention, or even that SEQ ID NO:1 in antisense orientation can be used to down regulate the orthologous gene in any other plant species, even ones in the same family as Arabidopsis.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

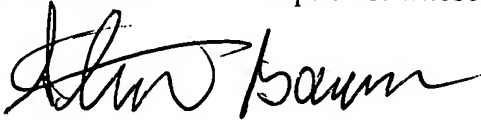
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read 'Stuart F. Baum', is written over the typed name.

Stuart F. Baum Ph.D.

Primary Examiner

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April 12, 2007

STUART F BAUM, PH.D.
PRIMARY EXAMINER